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| 10/588,323 | 02/16/2007 | Daniel Magilavy | 253780 | 2783 |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|---|
| Office Action Summary | Application No. 10/588,323 | Applicant(s) MAGILAVY, DANIEL |
| | Examiner Philip Gambel | Art Unit 1644 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03 August 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-30 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08-
 Paper No(s)/Mail Date 9/4/07, 1/2/08, 1/23/08)
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

1. Applicant's amendment, filed 08/03/2006, has been entered.

Claims 8-22 have been amended

Claims 1-30 are pending

2. Applicant is invited to amend the first line of the specification to incorporate the claim for priority and its relationship to PCT/US05/03907, filed 02/07/2005.

3. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ® or ™ symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

4. Claims 6, 23-27 and 29-30 are objected to because the claims rely upon the recitation of Figure 1 and not the appropriate SEQ ID NO(S). that read on the structure of AMEVIVE.

5. Claim 5-6, 23-27 and 29-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 5 is indefinite in reciting "the amino terminal 92 amino acids of mature LFA-3" , "the C-terminal amino acids of human IgG1 hinge region"because the referenced sequence (SEQ ID NO(S.) are not recited.

B) Claims 6, 23-27 and 29-30 contain the trademark or trade name "AMEVIVE". Where a trademark or trade name is used in a claims as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 USC 112, second paragraph, See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark or the trade name "AMEVIVE" is used to identify or describe a "LFA-3 polypeptide", and accordingly, the identification or the description is indefinite. The relationship between a trademark or tradename and the product it identifies may be uncertain and arbitrary. The formula or characteristics of the

Art Unit: 1644

product may change from time to time and yet it may continue to be sold under the same trademark or tradename.

Applicant is invited to claim the entire sequence of "AMEVIVE" to clarify the claims.

C) Applicant should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

It is apparent that the pSAB152 plasmid is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the appropriate plasmid. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

Upon reviewing the instant specification, applicant should note that the current ATCC Depository address is as follows:

American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209

Although pages 1-2, overlapping paragraph, and pages 7-10 of the instant specification appears to rely upon U.S. Patent No. 6,162,432 (1449; #A30) for the deposit of pSAB152 (ATCC 68720),

the record is not clear whether the conditions for the deposit of biological materials under 35 USC § 112, first paragraph, with respect to the deposit of pSAB152 (ATCC 68720) have been satisfied.

Art Unit: 1644

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Given the ambiguity concerning the effective priority date of all the instant claims, the prior art rejection under 35USC 102 is applied under 35 U.S.C. § 102(a)(b)(e), as indicated.

Art Unit: 1644

11. Claims 1-13 and 16-30 are rejected under 35 U.S.C. § 102 (a)(e) as being anticipated by Vaishnaw et al. (US 200401770635) (see entire document).

Vaishnaw et al. teach the LFA-3 polypeptide of the claimed invention (e.g., see paragraphs [0130] – [0156]) (also see AMEVIVE in paragraph [0203] and plasmid in [0209] 0 [0220], for the treatment of skin disorders, including psoriasis (e.g. paragraph [0002]- [0005], [0012]-[0014], [0028] [0040] –[0066], [0177]-[0183] encompassing multiple treatments via intramuscular and intravenous administration (e.g., see paragraphs [0050] – [0058], [0175] - [0181] and including kits and instructions comprising the LFA-3 polypeptide to treat psoriasis (e.g. paragraphs [0072] and [0196] – [0197].

With respect to the recitation of multiple cycles comprising administration periods and rest periods, including at least 4-8 cycles as well as 8-12 weeks;

the multiple treatments described by the prior art anticipate such claims,
given that multiple treatments necessarily require an administration period and a rest period.

With respect to the kit, the recitation of “a patient who has previously had two cycles of treatment with AMEVIVE” does not patentable weight to the claimed “kit”, in the absence of providing some structural distinction over the prior art compositions.

A composition is a composition irrespective of what its intended use is.

12. Claims 1-30 are rejected under 35 U.S.C. § 102(a)(b)(e) as being anticipated by Dingivan (US2003/0044406)(1449; #A1) (see entire document).

Dingivan teach the treatment of psoriasis (e.g., see paragraphs [0015] – [0022], [0150], with CD2 antagonists encompassed by the claimed LFA-3 polypeptides alefacept / AMEVIVE (e.g. paragraph 0163]-[0173], [0242]-[0279]]00

With multiple dosing (e.g., Summary of the Invention on pages 3-18; Detailed Description on pages 18- , including paragraphs [0139], [0144]-[0145], [[0294]-[0295], [0381]-[0461]], as well as kits with instructions ([0544] – [0558]).

Note, too, that Dingivan teaches the PASI score as a means to assess the severity of psoriasis (e.g., see paragraph [0028], [0123] – [0125], [0402], [0495], [0554]

With respect to the claimed recitation of multiple cycles comprising administration periods and rest periods, including at least 4-8 cycles, 8-12 weeks and years;

the multiple treatments as described by the prior art anticipate such claims,
given that multiple treatments necessarily require an administration period and a rest period and read on long term treatment to alleviate the severity of the chronic disease of psoriasis.

With respect to the kit, the recitation of “a patient who has previously had two cycles of treatment with AMEVIVE” does not patentable weight to the claimed “kit”, in the absence of providing some structural distinction over the prior art compositions.

A composition is a composition irrespective of what its intended use is.

Art Unit: 1644

13. Claims 1-30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Vaishnav et al. (US 200401770635) AND Dingivan (US 2003/0044406) (1449; #A1) in view of Magilavy (US 20020009446) (1449; #A3).

Vaishnav et al. teach the LFA-3 polypeptide (alefacept, AMEVIVE; see entire document) of the claimed invention (e.g., see paragraphs [0130] – [0156]) (also see AMEVIVE in paragraph [0203] and plasmid in [0209] 0 [0220],

for the treatment of skin disorders, including psoriasis (e.g. paragraph [0002]- [0005], [0012]- [0014], [0028] [0040] –[0066], [0177]-[0183]

encompassing multiple treatments via intramuscular and intravenous administration (e.g., see paragraphs [0050] – [0058], [0175] - [0181] and

including kits and instructions comprising the LFA-3 polypeptide to treat psoriasis (e.g. paragraphs [0072] and [0196] – [0197] (see entire document)..

Note that Example 3 of Vaishnav incorporates PASI improvement in the determination of correlating effective treatment by alefacept / AMEVIVE (e.g., see Example 3 on paragraphs [0203] – [0206])

Similarly to the teachings of Vaishnav et al.

Dingivan teach the treatment of psoriasis (e.g., see paragraphs [0015] – [0022], [0150], with CD2 antagonists encompassed by the claimed LFA-3 polypeptides alefacept / AMEVIVE (e.g. paragraph 0163]-[0173], [0242]-[0279]

with multiple dosing (e.g., Summary of the Invention on pages 3-18; Detailed Description on pages 18- , including paragraphs [0139], [0144]-[0145], [[0294]-[0295], [0381]-[0461]], as well as kits with instructions ([0544] – [0558].

Note, too, that Dingivan teaches the PASI score as a means to assess the severity of psoriasis (e.g., see paragraph [0028], [0123] – [0125], [0402], [0495], [0554]

Magilavy teach the use of the CD2 binding agents of the claimed invention (e.g., LFA3TIP, see pages 20-26 and page 38) for the treatment of inflammatory conditions

that can be administered in dosing and modes of administration that appear to be the same or nearly the same as claimed, such that the dosing and modes of administration are continued until the desired effect is achieved (e.g., see pages 30-33) (see entire document).

Although Magilavy does not disclose psoriasis per se, Magilavy does teach psoriatic arthritis and dermatitis and inflammatory conditions associated with T cells, which is consistent with the inflammatory conditions associated with psoriasis (e.g., see Summary of the Invention on pages 5-6). Note, too, that Magilavy recognizes that PSAI scores as well as nail evaluation are assessed with skin lesions by the dermatologist for efficacy (e.g., see Example V on pages 46-52, including page 50).

Art Unit: 1644

With respect to the recitation of multiple cycles comprising administration periods and rest periods and long term treatment,

the multiple treatments described by the prior art render obviousness such claims,

given that multiple treatments necessarily require an administration period and a rest period and are required over a long time in order to alleviate the chronic disease of psoriasis.

As to the use of multiple courses of administering LFA-3 polypeptides for a chronic disease such as psoriasis,

such dosing and modes of administration are result effective variables.

It is well settled that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980). See also Merck & Co. v. Biocraft Labs. Inc., 874 F.2d 804, 809, 10 USPQ2d 1843, 1847-48 (Fed. Cir. 1989) (determination of suitable dosage amounts in diuretic compositions considered a matter of routine experimentation and therefore obvious).

As dosing and modes of administration are known to the ordinary artisan, it would have been obvious to optimize both the dosing regimens and mode of administration to meet the needs of the patient at the time the invention was made.

Given the clear teachings of the prior art to treat psoriasis with immunosuppressive LFA-3 polypeptides in order to meet the needs of the patients, including teachings of multiple dosing and therapeutic endpoints of reducing the severity of a chronic disease as well as reliance upon criteria such as PSAI scores;

one of ordinary skill in the art at the time the invention was made would have been motivated to administer immunosuppressant LFA-3 polypeptides over long periods of time, including weeks and years, in order to treat a chronic disease such as psoriasis.

The various dosing regimens encompassed by the instant claims were obvious at the time the invention was made, given that it was well known and practice at the time the invention was made to provide immunosuppressive therapy based upon the condition and needs of the patient, as evidenced by the teachings of the prior art.

With respect to the kit, the recitation of "a patient who has previously had two cycles of treatment with AMEVIVE" does not patentable weight to the claimed "kit", in the absence of providing some structural distinction over the prior art compositions.

A composition is a composition irrespective of what its intended use is.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Art Unit: 1644

"The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." See In re Rosselet, 146 USPQ 183, 186 (CCPA 1965).

"There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." Motorola, Inc. v. Interdigital Tech. Corp., 43 USPQ2d 1481, 1489 (Fed. Cir. 1997).

An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int'l Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

Given that the prior art goal was to inhibit immune responses in patients with psoriasis with immunosuppressant LFA-3 polypeptides,

incorporating multiple courses of immunosuppressant LFA-3 over a long time would have been routine to the ordinary artisan at the time the invention was made and therefore obvious in designing such methods to effectively treat, manage or ameliorate a chronic disease / condition such as psoriasis.

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of USSN 11/398,908.

Although the copending claims differ in the targeted diseases, all of the claims rely upon the same AMEVIVE, LFA-3 antagonists to treat inflammatory conditions, including psoriasis in the instant application and psoriatic arthritis and dermatitis in the copending application. Modes of administration and dosing are obvious over one another in that the ordinary artisan would have provided the appropriate effective amounts to achieve therapeutic end results of reducing severity of an inflammatory condition, including the chronic inflammatory conditions encompassed by the claimed methods. Therefore, treating the various inflammatory conditions with the same LFA-3 antagonists would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/

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Art Unit 1644
September 30, 2008

Application/Control Number: 10/588,323

Art Unit: 1644

Page 10